

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re Sitagliptin Phosphate ('708 & '921)
Patent Litigation

C.A. No. 19-md-2902-RGA

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

C.A. No. 20-cv-749-RGA

**APOTEX INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES AND
COUNTERCLAIMS TO FIRST AMENDED COMPLAINT**

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by and through their counsel, hereby answer and respond to each of the allegations of the First Amended Complaint of Plaintiff Merck Sharp & Dohme Corp. ("Merck") (D.I. 59), and assert their affirmative defenses as follows:

1. Apotex admits this is an action for purported patent infringement arising under the patents laws of the United States, Title 35 of the United States Code, and for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patents laws of the United States, Title 35 of the United States Code, arising out of Apotex's submission of ANDA No. 214494 seeking FDA approval for metformin hydrochloride, sitagliptin phosphate extended release tablets prior to the expiration of U.S. Patent Nos. 7,326,708 and 7,468,459. Otherwise, denied.

2. Admitted.

3. Admitted.

4. Apotex admits that the reference listed drug for ANDA No. 214494 is JANUVIA XR®. This paragraph otherwise contains conclusions of law, for which no response is required. To the extent a response is required, denied.

PARTIES

5. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

6. Apotex admits that Merck is listed by the FDA as the applicant holder of NDA No. 202270 for JANUVIA XR®, which was approved by the FDA.

7. Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, having corporate offices and its principal place of business at 150 Signet Drive, Toronto, Ontario Canada M9L 1T9. This paragraph otherwise contains conclusions of law, for which no response is required. To the extent a response is required, denied.

8. Apotex admits that Apotex Corp. is a Delaware corporation with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. This paragraph otherwise contains conclusions of law, for which no response is required. To the extent a response is required, denied.

9. This paragraph contains conclusions of law, for which no response is required. To the extent a response is required, denied.

10. This paragraph contains conclusions of law, for which no response is required. To the extent a response is required, denied.

11. This paragraph contains conclusions of law, for which no response is required. To the extent a response is required, denied.

12. This paragraph contains conclusions of law, for which no response is required. To the extent a response is required, denied.

JURISDICTION

13. Admitted.

14. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purposes of this action only. Otherwise, denied.

15. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purposes of this action only. Otherwise, denied.

16. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purposes of this action only. Otherwise, denied.

17. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purposes of this action only. Otherwise, denied.

18. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purposes of this action only. Otherwise, denied.

19. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purposes of this action only. Otherwise, denied.

VENUE

20. Apotex incorporates each of its responses to the preceding paragraphs 1-19 as if fully set forth herein.

21. Solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this judicial district for the limited purposes of this action only. Otherwise, denied.

22. Solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this judicial district for the limited purposes of this action only. Otherwise, denied.

THE '708 PATENT

23. Apotex incorporates each of its responses to the preceding paragraphs 1-22 as if fully set forth herein.

24. Apotex admits that Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr. are listed as inventors on the face of the '708 patent.

25. Apotex admits that the '708 patent is entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor," and issued on February 5, 2008. Otherwise denied.

26. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

27. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

28. Apotex admits that the '708 patent is listed in the FDA's Orange Book in connection with JANUMET XR®. Otherwise denied.

THE '459 PATENT

29. Apotex incorporates each of its responses to the preceding paragraphs 1-28 as if fully set forth herein.

30. Apotex admits that Yi Xiao, Joseph Armstrong, Shane Krska, Eugenia Njolito, Nelo Rivera, Yongkui Sun, and Thorsten Rosner are listed as inventors on the face of the '459 patent.

31. Apotex admits that the '459 patent is entitled "Process for the Preparation of Chiral Beta Amino Acid Derivatives by Asymmetric Hydrogenation," and issued on December 23, 2008. Otherwise denied.

32. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

33. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

COUNT I – INFRINGEMENT OF THE '708 PATENT

34. Apotex incorporates each of its responses to the preceding paragraphs 1-33 as if fully set forth herein.

35. Apotex admits that it notified Merck of its submission of Apotex's ANDA seeking FDA approval prior to the expiration of the '708 patent. This paragraph otherwise contains conclusions of law, for which no response is required.

36. Admitted.

37. Admitted.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

**COUNT II – DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '708 PATENT**

51. Apotex incorporates each of its responses to the preceding paragraphs 1-50 as if fully set forth herein.

52. This paragraph contains conclusions of law, for which no response is required.

53. Denied.

**COUNT III – DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '459 PATENT**

54. Apotex incorporates each of its responses to the preceding paragraphs 1-53 as if fully set forth herein.

55. This paragraph contains conclusions of law, for which no response is required.

56. Apotex admits that Signa S.A. de C.V is the owner of DMF No. 32298. Otherwise, denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Apotex is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. It is further denied that Plaintiff is entitled to the relief requested in the First Amended Complaint or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the First Amended Complaint not expressly admitted, Apotex asserts the following separate defenses to the First Amended Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST AFFIRMATIVE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the '708 and '459 patents are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

THIRD AFFIRMATIVE DEFENSE

Apotex has not directly or indirectly infringed any valid or enforceable claim of the '708 and '459 patents. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Apotex's ANDA No. 214494 does not and will not infringe any valid or enforceable claim of the '708 and '459 patents, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to attorney's fees, or any other award, because Plaintiff has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285 as it relates to Plaintiff.

FIFTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this case.

SIXTH AFFIRMATIVE DEFENSE

Apotex reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

COUNTERCLAIMS

Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp., (collectively, “Apotex”) for their Counterclaims against Plaintiff/Counterclaim Defendant Merck Sharp & Dohme Corp. (“Counterclaim Defendant” or “Merck”), allege as follows:

1. This is a counterclaim for declaratory judgment of noninfringement and/or invalidity of one or more claims of U.S. Patent Nos. 7,326,708 (“the ’708 patent”) and 7,468,459 (“the ’459 patent”).

THE PARTIES

2. Apotex Inc. is a Canadian corporation, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, and based on the allegations in the First Amended Complaint, Merck is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

JURISDICTION AND VENUE

5. Apotex seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

6. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271(e)(2).

7. This is an action based on an actual controversy between Apotex and Counterclaim Defendant concerning the noninfringement and/or invalidity of the ’708 and ’459 patents arising

under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and Apotex's right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 214494, and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the products that are the subject of Apotex's ANDA No. 214494 ("Apotex's ANDA Products").

8. The Court has personal jurisdiction over Counterclaim Defendant because, on information and belief, Counterclaim Defendant transacts business within the State of Delaware and/or has engaged in systematic and continuous business contacts within the State of Delaware. Further, Counterclaim Defendant has subjected itself to the jurisdiction of this Court by virtue of filing the First Amended Complaint.

9. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Counterclaim Defendant's choice of forum.

BACKGROUND

10. Apotex incorporates each of its responses to each paragraph of the First Amended Complaint, as well as the foregoing paragraphs 1-9 of the Counterclaims, as if fully set forth herein.

11. On information and belief, Counterclaim Defendant caused the FDA to list the '708 patent in the FDA's Orange Book publication in connection with JANUMET XR®.

12. By maintaining the listing of the '708 patent in the Orange Book, Counterclaim Defendant represents that claims of infringement of the '708 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(G).

13. On information and belief, Counterclaim Defendant has not caused the FDA to remove the '708 patent from the Orange Book in connection with JANUMET XR®.

14. By letter dated May 6, 2020, Apotex timely notified Counterclaim Defendant that it had submitted ANDA No. 214494 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '708 patent ("Notice Letter"). Apotex's Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Apotex's opinion that the claims of the '708 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products. Apotex incorporates by reference its Notice Letter.

15. On June 3, 2020, Counterclaim Defendant filed an infringement action against Apotex alleging infringement of the '708 patent.

16. On February 17, 2021, Counterclaim Defendant filed the First Amended Complaint against Apotex alleging infringement of the '708 and '459 patents.

17. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Apotex and Counterclaim Defendant having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the '708 and '459 patents, and as to Apotex's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products.

COUNT I
Declaratory Judgment of Noninfringement of the '459 Patent

18. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–17 of its Counterclaims.

19. Counterclaim Defendants have accused Apotex of infringing claims of the '459 patent in connection with ANDA No. 214494.

20. Apotex denies infringement of any valid, enforceable, properly construed claim of the '459 patent and alleges that Apotex has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '459 patent.

21. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Apotex's ANDA Products will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '459 patent.

22. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not, and would not if marketed, infringe any valid and/or enforceable claim of the '459 patent.

COUNT II
Declaratory Judgment of Invalidity of the '459 Patent

23. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–22 of its Counterclaims.

24. The claims of the '459 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation.

25. Apotex is entitled to a judicial declaration that the claims of the '459 patent are invalid.

COUNT III
Declaratory Judgment of Noninfringement of the '708 Patent

26. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–25 of its Counterclaims.

27. Counterclaim Defendants have accused Apotex of infringing claims of the '708 patent in connection with ANDA No. 214494.

28. Apotex denies infringement of any valid, enforceable, properly construed claim of the '708 patent and alleges that Apotex has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '708 patent.

29. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Apotex's ANDA Products will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '708 patent.

30. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not, and would not if marketed, infringe any valid and/or enforceable claim of the '708 patent.

COUNT IV
Declaratory Judgment of Invalidity of the '708 Patent

31. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–30 of its Counterclaims.

32. The claims of the '708 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, and including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letters.

33. Apotex is entitled to a judicial declaration that the claims of the '708 patent are invalid.

EXCEPTIONAL CASE

This case is an exceptional one, and Apotex is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Apotex prays that the Court enter judgment in its favor and against Plaintiff/Counterclaim Defendant as follows:

- a) Dismissing the First Amended Complaint with prejudice and denying each request for relief made by Plaintiff/Counterclaim Defendant therein;
- b) Declaring that the claims of the '708 patent are invalid;
- c) Declaring that the claims of the '459 patent are invalid;
- d) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Apotex ANDA Products has not infringed, does not infringe, and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claims of the '459 patent;
- e) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Apotex ANDA Products has not infringed, does not infringe, and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claims of the '708 patent;
- f) Granting Apotex judgment in its favor on Plaintiff/Counterclaim Defendant's claims;
- g) Granting Apotex judgment in its favor on its own Counterclaims;

- h) Declaring that this is an exceptional case in favor of Apotex pursuant to 35 U.S.C. § 285;
- i) Declaring that Apotex is the prevailing party and awarding costs, attorneys' fees, and expenses to Apotex; and
- j) Awarding Apotex such other and further relief to which it may be entitled.

Dated: March 4, 2021

Of Counsel

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**PHILLIPS, MCLAUGHLIN
& HALL, P.A.**

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